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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/997,594	11/29/2001	Esha A. Gangolli	21402-213 (CURA-513)	5131

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EXAMINER	
SNEDDEN, SHERIDAN	
ART UNIT	**PAPER NUMBER**
1653	

DATE MAILED: 12/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/997,594	GANGOLLI ET AL.	
	Examiner	Art Unit	
	Sheridan K Snedden	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-41 is/are pending in the application.

4a) Of the above claim(s) none is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-41 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Applicant's amendment of claims 1-3, 5, 8-10 filed 28 October 2002 is acknowledged. Claims 1-41 are pending.

Election/Restrictions

2. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-5, 29, 32, drawn to a protein of SEQ ID NO: 10, classified in class 530, subclass 350+.

II. Claims 6-14, 30, 33, drawn to a nucleic acid molecule of SEQ ID NO: 9, vector and host cell, classified in class 435, subclass 69.1.

III. Claims 15-17, 31, 34, drawn to an antibody, classified in class 530, subclass 387.1.

IV. Claim 18, drawn to a method for determining the presence of a protein, classified in class 435, subclass 7.1.

V. Claim 19, drawn to a method for determining the presence of a nucleic acid, classified in class 435, subclass 6.

VI. Claim 20 and 22, drawn to a method of identifying an agent that binds a polypeptide, classified in class 435, subclass 7.1.

VII. Claim 21, drawn to a method of identifying an agent that modulates that expression or activity of the protein, classified in class 435, subclass 6.

VIII. Claims 23-24, 40, drawn to a method of treatment with a protein, classified in class 514, subclass 2.

IX. Claims 25-26, drawn to a method of treatment with a nucleic acid, classified in class 514, subclass 44.

X. Claims 27-28, 41, drawn to a method of treatment by administration with an antibody that binds to any one of SEQ ID NO: 10, classified in class 514, subclass 1.

XI. Claim 35, drawn to a method of making a therapeutic with a polypeptide of SEQ ID NO: 10, classified in class 514, subclass 1.

XII. Claim 35, drawn to a method of making a therapeutic with a nucleic acid of SEQ ID NO: 9, classified in class 514, subclass 1.

XIII. Claim 35, drawn to a method of making a therapeutic with an antibody that binds to SEQ ID NO: 10, classified in class 514, subclass 1.

XIV. Claims 36-39 drawn to a method of screening for a disorder with an animal that recombinantly expresses a polypeptide of SEQ ID NO: 10, classified in class 514, subclass 1.

3. The inventions are distinct, each from the other because of the following reasons:

The nucleic acids of invention II are related to the protein of invention I by virtue of encoding same. The DNA molecule has utility for the recombinant production of the protein in a host cell, as recited in the claims of invention II. Although the DNA molecule and protein are related since the DNA encodes the specifically claimed protein, they are distinct inventions because the protein product can be made by another and materially different process, such as by synthetic peptide synthesis or purification from the natural source. Further, the DNA may be

used for processes other than the production of the protein, such as nucleic acid hybridization assay. Thus, they can be unconnected in use and operation.

The protein of invention I are related to the antibody of invention III by virtue of being the cognate antigen, necessary for the production of antibodies. Although the protein and antibody are related due to the necessary stearic complementarity of the two, they are distinct inventions because the protein can be used in another and materially different process from the use for the production of the antibody, such as in a pharmaceutical composition in its own right, or to assay or purify the natural ligand of the protein (if the protein is itself a receptor), or in assays for the identification of agonists or antagonists of the receptor protein.

The nucleic acid of invention II and the antibody of invention III are related by virtue of the protein that is encoded by the nucleic acid and necessary for the production of the antibody. However, the nucleic acid itself is not necessary for antibody production and both are wholly different compounds having different compositions and functions. Therefore, these inventions are distinct.

Inventions I and IV, VI-VIII, XI and XIV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polypeptides of invention I can be used in a materially different process such as generating antibodies, as in invention III, or in any one of inventions IV, VI-VIII, XI and XIV, for example.

Invention II discloses a method for detecting the product of invention V and are thus related. However, the inventions are patentably distinct because the product of invention II need not be present during the detection process and thus the method of invention V can neither utilize the products of invention II nor be used to make such products.

Inventions I is related to inventions IX and XII as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acid molecules can be used to make the protein of Invention I, or in either of inventions IX and XII, for example.

Inventions III is related to inventions X and XIII as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibodies can be used to make secondary antibodies, or in either of inventions X and XIII, for example.

The product of invention I is not used in the method of inventions V, IX, X, XII and XIII. Therefore, invention I is patentably distinct from invention V, IX, X, XII and XIII.

The product of invention II is not used in the method of inventions IV, VI-VIII, X, XI, XIII and XIV. Therefore, invention I is patentably distinct from invention IV, VI-VIII, X, XI, XIII and XIV

The product of invention III is not used in the method of inventions IV-IX, XI, XII, and XIV. Therefore, invention I is patentably distinct from invention IV-IX, XI, XII, and XIV.

The methods of inventions IV-XIV require different products and steps and have different endpoints. Therefore, inventions IV-XIV are patentably distinct.

4. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Groups II-XIV, restriction for examination purposes as indicated is proper.

5. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312. In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be

maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Advisory Information

6. A telephone call was made to Cynthia Kozakiewitcz on November 30, 2003 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sheridan K Snedden whose telephone number is (703) 305-4843. The examiner can normally be reached on Monday - Friday, 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 746-3975 for regular communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

SKS
December 1, 2003

SKS

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER